



C. Earl Hunter, Commissioner

*Promoting and protecting the health of the public and the environment.*

January 20, 2012

MEMORANDUM

TO: X-Ray Facilities  
X-Ray Service Providers

FROM: Charles G. Ditmer, Director  
Division of Electronic Products  
Bureau of Radiological Health

SUBJECT: HAND HELD X-Ray Devices – Guidelines of use Requirements

The Department of Health and Environmental Control, Bureau of Radiological Health has reviewed a proposal to sell and market the ARIBEX NOMAD Hand Held Portable X-Ray device in the state of South Carolina. The Bureau has determined that in certain situations this unit could be a useful diagnostic imaging tool. The following requirements must be followed for the use and sale of the unit in South Carolina to Facilities and Vendors.

- 1) The ARIBEX Corporation must follow all vendor requirements outlined in Title B Regulations.
- 2) ARIBEX may only market NOMAD models manufactured on or after June 1, 2007, for sale or use in the state of South Carolina.
- 3) A copy of this letter must be distributed with all units sold to South Carolina Facilities and any Company (Vendors) that plan to sell the unit in South Carolina.
- 4) All literature regarding the use of the NOMAD including training CD's distributed by the manufacturer to end users must be reviewed and accepted by the Bureau of Radiological Health before the NOMAD can be sold in South Carolina.
- 5) Each operator must complete the training program supplied by the manufacturer and accepted by the Department prior to using the x-ray unit. Records of the training shall be maintained on file for review by the Department.
- 6) The **ARIBEX NOMAD Pro**, manufactured after January 2008, is the only hand held device that is accepted for routine radiographic procedures in facilities. To ensure radiation safety, only the x-ray operator and the patient will be present in the room during the x-ray exposure(s). **All other models of the ARIBEX NOMAD hand held dental x-ray device shall not be used for routine radiographic procedures in facilities.**

- 7) Only the **ARIBEX NOMAD Pro**, manufactured after January 2008, can be utilized for both office and portable imaging. All other models of the ARIBEX NOMAD hand held dental x-ray device are restricted to be used only in a setting where normal operating systems cannot be obtained, such as a nursing home, extended residential care facility, home bound patients, or special needs patients.
- 8) The Aribex NOMAD may only be used in conjunction with "F-speed" film, phosphorus or digital image receptors to further minimize patient and operator radiation exposure.
- 9) All operators of the NOMAD unit must have protective shielding of at least 0.5 millimeters lead equivalence to protect the gonads, torso, thyroid, and eyes, from scattered radiation. All operators must properly wear radiation monitoring badges, including a finger ring badge.
- 10) Facilities that wish to purchase the NOMAD unit must follow all registration requirements and obtain Facility Registration Approval from this Department. **Vendors that want to sell the unit in South Carolina must be registered with this Department.**
- 11) All operators of the unit must meet the requirements of the South Carolina Dental Board. Registrants of the NOMAD must secure the device in a safe location that prevents unauthorized use of the NOMAD.
- 12) The NOMAD unit must have an Equipment Performance Test done annually (Appendix F, Title B Regulations).
- 13) The NOMAD must be used with the scatter shield in place in order to minimize scatter radiation exposure to the operator at all times.
- 14) In the event a facility elects to use the Aribex NOMAD Pro for routine radiographic use, the facility will be required to obtain a variance approval from this Department regarding Regulation 61-64, Section 1.2.8 which states:

*It shall be unlawful to use hand-held radiographic or fluoroscopic imaging devices, or hand-held therapy units, except for contact therapy units operated according to Part VI of these regulations.*

The variance approval letter from the Department must be obtained prior to the use, sale or purchase of the device for routine use.

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Please keep in mind, currently the ARIBEX NOMAD Portable Dental X-Ray machine is the only hand held x-ray device for human use that has been accepted by this Department. Other hand held x-ray devices will need to go through an acceptance review process.

Any person, manufacturer, dealer, or registrant who fails to abide by the requirements outlined in this document may be subject to enforcement actions including the potential for civil penalties being assessed for permitting unnecessary radiation exposure.

If you have any questions regarding this matter, please feel free to contact this Department at 803-545-4400.